IX. 510(k) Summary

JUN 2 6 2002

SUBMITTER: DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, MA 02767

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: June 4, 2002

CLASSIFICATION NAME: Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation

PROPRIETARY NAME: CrossOver Cross Connector

PREDICATE DEVICES: CrossOver Cross Connector (K013296)

DEVICE DESCRIPTION: The CrossOver Cross Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 5.0mm and 6.35mm spinal rods of the Moss Miami Spine System

INTENDED USE: The Moss Miami Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Moss Miami Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with

	removal of the implants after the attainment of a solid fusion. The Moss Miami Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).
MATERIALS:	Manufactured from ASTM F-138 implant grade stainless steel.
PERFORMANCE DATA:	Performance data were submitted to characterize the CrossOver Cross Connector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K021880
Trade/Device Name: CrossOver Cross Connector (Moss Miami Spinal System)
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: June 5, 2002
Received: June 7, 2002

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K021880

Device Name: CrossOver Cross Connector

Indications For Use:

The Moss Miami Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021880

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)